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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,052	06/29/2001	Frank J. Bunick	MCP-281	9476

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EXAMINER	
OH, SIMON J	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/896,052	BUNICK ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, response, and petition for extension of time, all received on 23 April 2007.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-25 under 35 U.S.C. 103(a) over the combined disclosures of Lee (U.S. Patent No. 6,060,078) and Mehta (U.S. Patent No. 4,800,087) is hereby withdrawn.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (U.S. Patent No. 6,060,078) in view of Mehta (U.S. Patent No. 4,800,087), Silva *et al.* (U.S. Patent No. 4,753,790), and Mackles (U.S. Patent No. 4,260,596).

Lee teaches a chewable pharmaceutical dosage form comprising of a core containing an active ingredient, and an outer layer (See Figure 2). The dosage form demonstrates improved organoleptic properties when chewed, such as taste (See Column 1, Lines 47-52). The core may be in the form of a jelly, with the base of the jelly selected from a group that includes pectin (See Column 2, Lines 29-33). In addition, gelatin may be used in either the core or outer layer to maintain hardness and extension property in the dosage form (See Column 2, Lines 59-61). The outer layer may take a variety of forms, including hard candy (See Column 2, Lines 34-42).

Acetaminophen is listed as a possible active ingredient in the core (See Column 2, Lines 9-18). In addition, Lee contains what the examiner will interpret as an enabling disclosure of a dosage form with a unitary core (See Figure 2; and MPEP § 2125). The disclosed invention has the advantage of having an improved chewing property, which the examiner broadly interprets as having a texture masking property, in addition to having a taste masking property (See Column 3, Lines 53-58).

The Lee patent does not teach the use of ibuprofen in the disclosed dosage form, nor does it expressly disclose particles sizes for the active agent. The Lee patent does not teach the use of an outer shell that is about 20% to about 50% of the total weight of the dosage form, nor does it teach that such an outer shell has a thickness of about 500 to 3000 microns.

Mehta teaches a chewable, taste-masked pharmaceutical dosage form, preferably in the form of a tablet (See Column 1, Lines 6-28). The components of this dosage form consist of taste-masked microcapsules, which may then be prepared as chewable tablets. The microcapsules themselves comprise a polymeric coating that masks the taste of the active ingredient, and a pharmaceutical core (See Column 4, Lines 4-12; and Examples 1 and 2). In one embodiment, the polymeric coating may be composed of a low-temperature film-forming polymer that produces a film at temperatures below 25°C., in order to produce microcapsules ranging in size from 10 microns to 1.5 mm in diameter (See Column 5, Lines 49-66). Acetaminophen and ibuprofen are listed among suitable drugs for use in the reference (See Column 7, Lines 31-48; and Claims 11 and 12). Diluents acceptable for use in the microcapsule core include gelatin (See Column 7, Line 59 to Column 8, Line 12). In the given examples, the preferred size of the uncoated acetaminophen particles used lies in the range of 150 to 300

microns (See Column 10, Lines 45-47). The reference also teaches that the coated pharmaceutical cores may then be encapsulated in a hard gelatin capsule or further coated with candy (See Column 9, Lines 35-40).

The Silva *et al.* patent discloses a coated comestible having a hard outer shell (See Abstract). The dosage form comprises a core that is coated with the shell, where the core can be in various forms, such as gums, candies, jellies, and pills or tablets used for medicinal purposes (See Column 3, Lines 20-32). In the examples provided, the final coated products have an outer shell in a quantity that ranges from approximately 20% to 40% by weight of the product (See Examples I to V; and Tables 5, 9, 13, 17 and 18).

The Mackles patent teaches an edible unit dosage form having an outer shell and a liquid or gel center containing an active agent (See Abstract; and Figures). Although the thickness of the shell may vary, it is generally in the range of about 0.5 to about 3.0 mm (See Column 2, Lines 57-61).

It would be obvious to one of ordinary skill in the art to combine the teachings of Lee, Mehta, Silva *et al.*, and Mackles into the objects of the instant application. Both the Lee and Mehta patents deal with the administrations of drugs in pharmaceutical compositions with improved organoleptic properties. Therefore, one of ordinary skill would be motivated to incorporate the microcapsules disclosed in Mehta into the dosage form of Lee in order to provide a pharmaceutical dosage form wherein the active ingredient is further taste-masked without an undue delay on the release of the drug. As Mehta states that the disclosed compositions may be incorporated into chewable tablets, in the view of the examiner, this disclosure provides sufficient guidance to one of ordinary skill in the art to incorporate them into the chewable

dosage form taught in Lee. As such, it is the position of the examiner that one of ordinary skill in the art could combine the disclosures of the prior art with a reasonable expectation of success.

One of ordinary skill in the art would be motivated to incorporate the teachings of Silva *et al.* and Mackles into the disclosure of Lee, as Silva *et al.* and Mackles provide specific guidance as to how one of ordinary skill in the art may construct an outer shell for an edible dosage form. Such guidance would therefore lead one of ordinary skill in the art to provide are more carefully constructed outer shell that having improved organoleptic properties for the purpose of increasing patient acceptance and compliance. As Lee, Silva *et al.* and Mackles provide for dosage forms having a hard outer shell and softer core, they are analogous. Therefore, one of ordinary skill in the art would have a reasonable expectation of success in combining the references together.

The adjustment and optimization of parameters such as hardness of the soft core and the weight ratio of active agent particles are considered by the examiner to be well within the purview of one of ordinary skill in the art. Therefore, claim limitations drawn to such features are not considered by the examiner to impart a patentable quality unto the instantly claimed invention.

Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments with respect to Claims 1-25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
Art Unit 1618

sjo

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER